

(1) The Director and Deputy Director of the Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(3) Director, Division of Compliance Operations, Office of Compliance and Surveillance, CDRH.

(4) The Director, Division of Standards Enforcement, Office of Compliance and Surveillance, CDRH.

(5) Regional Food and Drug Directors; District Directors; the Director, St. Louis Branch; the Director, Northeast Regional Laboratory, Northeast Region; the Director, Southeast Regional Laboratory, Southeast Region; the Director, Winchester Engineering and Analytical Center; and the Director, National Forensic Chemistry Center, when such functions relate to:

(i) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter; and

(ii) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product as defined in § 1040.20(b) of this chapter.

[48 FR 8441, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14933, 14936, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8317, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990; 57 FR 40318, Sept. 3, 1992; 59 FR 42491, Aug. 18, 1994; 60 FR 15871, Mar. 28, 1995]

§ 5.38 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs, new animal drugs, and feeds bearing or containing new animal drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) regarding the issuance of written notices.

(1) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Director, Division of Drug Labeling Compliance, Office of Compliance, CDER.

(4) The Director and Deputy Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER.

(5) The Director and Deputy Director, Division of Drug Quality Evaluation, Office of Compliance, CDER.

(6) The Director and Deputy Director, Division of Scientific Investigations, Office of Compliance, CDER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under sections 512(e) and 512 (m)(4)(B)(ii) and (m)(4)(B)(iii) of the act regarding the issuance of written notices.

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(3) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(4) Regional Food and Drug Directors.

(5) District Directors.

[57 FR 18823, May 1, 1992]

§ 5.39 Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.

The following officials are authorized to perform all the functions of the Director, Center for Biologics Evaluation and Research (CBER) with regard to program authorities for their respective areas:

(a) Associate Directors, CBER.

(b) Office Directors, CBER.

(c) Division Directors, CBER.

[58 FR 18346, Apr. 9, 1993]

§ 5.44 Export of unapproved drugs.

(a) The following officials are authorized, under section 802(b) of the Federal Food, Drug, and Cosmetic Act, to approve or disapprove applications to export unapproved new drugs and biological products and to issue notices of receipt of such applications:

(1) For human drugs assigned to their respective organizations:

(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Director, Office of Compliance, CBER.